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K00068

# SECTION 2. SUMMARY AND CERTIFICATION

## *A. 510(K) SUMMARY*

### Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Pty., Ltd. Summary for the Compumedics EEG System.

| | |
|---|---|
| SUBMITTER'S NAME: | Compumedics Pty. Ltd. |
| ADDRESS: | 1 Marine Parade<br>Abbotsford, Victoria, 3067<br>Australia |
| CONTACT PERSON: | Constance Bundy, C.G. Bundy Associates, Inc. |
| TELEPHONE NUMBER: | 612-574-1976 |
| FAX NUMBER: | 612-571-2437 |
| DATE OF SUBMISSION: | January 7, 2000 |

**1. Identification of device**

Proprietary Name: Compumedics E-Series EEG System

Common Name: EEG System

Classification Status: Class II per regulations 882.1400

Product Codes: GWQ

**2. Equivalent devices**

Compumedics believes the Compumedics EEG System is substantially equivalent to Nihon Kohden Polygraph EEG, 510(k) K983072

**3. Description of the Device**

The Compumedics EEG System is a device used to collect and store patient EEG signals as an aid in the diagnosis of neurological disorders by a neurologist. Electrodes from the patient are connected to a Patient Interface Box (PIB) that can provide up to 64 inputs plus 2 reference electrodes, which are used to reduce the patient common mode signal amplitude. The patient signals are amplified, filtered and digitized and passed on to the Control Box.

The Control Box controls the transmission of data between:

a) The PIB and the Recording Workstation
b) The Recording Workstation and the Photic Strobe – used to stimulate neurological functions
c) The Seizure button and the Recording Workstation – used to indicate specific patient events
d) Any non-isolated analogue signals from other devices to the Recording Workstation

It also controls the Patient Interface functions, including electrode impedance testing and calibration; the provision of isolated power to the PIB; and the digitizing of any non-isolated analogue signals from other devices.

The Recording Workstation displays the input patient signals on the monitor screen and stores the data on the computer hard disk for later retrieval and analysis. Once analyzed, the data can be archived to a backup medium such as an optical disk. Special features include the ability to produce a summary of the recorded data, the ability to edit the recorded data, and special analysis tools for spectral analysis and brain mapping.

## 4. Intended use

The Compumedics EEG System is intended for use by neurologists in private practices or hospital environments to assist in the diagnosis of various neurological disorders.

## 5. Technological characteristics, comparison to predicate device

Like the predicate device, the Compumedics EEG System is intended to detect brain waves from various points on the patient's scalp, individually or as a signal measured between selected electrodes, and to record those signals in accordance with preset parameters (in a montage) for later analysis by a neurologist. It is an aid only in the diagnosis of neurological disorders and will not prevent or restore the interruption or loss of any physiological system.

**Comparison Table:**

| Characteristic | Nihon Kohden EEG 2100 (digital) | Compumedics E-Series EEG |
|---|---|---|
| | | |
| **Configuration** | Mobile Cart | Mobile Cart or desktop |
| | | |
| **Headbox/preamp Configuration** | Isolated amplifier with digital output | 64 or 32ch Isolated amplifier with digital output |
| | | |
| **Number of channels** | 40 recordable, 32 display | 64 recordable/displayed/isolated<br>10 non-isolated/recordable |
| | | |
| **Montage Selection** | 32 switchable, 4 free | 256 programmable |
| | | |
| **Sensitivity Controls** | Yes | Yes |
| | | |
| **Low-Freq Filters** | Yes | Yes |
| | | |
| **High-Freq Filters** | Yes | Yes |
| | | |

| | | |
|---|---|---|
| **Master Notch Filter** | Yes | Yes |
| | | |
| **Noise Filters** | Yes | Yes |
| | | |
| **Electrode Imped. Check** | Yes | Yes |
| | | |
| **Calibration Check** | Yes | Yes |
| | | |
| **System Types** | Portable | Laboratory based or Portable |
| | | |
| **Time Base Controls** | Yes | Yes |
| | | |
| **Selectable Montage Sequences** | No | Yes |
| | | |
| **Photic Controls with selectable settings** | Yes | Yes |
| | | |
| **Automatic Event Logging** | Yes | Yes |
| | | |
| **Annotations on study** | N/A | Yes |
| | | |
| **Timers on study events** | Yes | Yes |
| | | |
| **Storage** | Optical disk, hard disk, floppy disk, continuous paper optional | Hard disk, writable CD, optical disk |
| | | |
| **Study Modes** | Routine EEG Recording | Routine EEG Recording, Long Term Monitoring, Retrieval and Replay |
| | | |
| **Processor** | Intel 486, Intel Pentium | Intel Pentium III |
| | | |
| **Optional Equipment** | Continuous feed printer | Time Sync Video/Digital Video/Printer/Remote Seizure Button |
| | | |

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## 6. Discussion of performance testing

An extensive collection of tests has been conducted and successfully completed, including:

- Safety Tests to conform to IEC 60601-1 (1988-12), IEC60601-2-26 (1994-04) to ensure that there is no potential for detrimental effects on patients, other persons, animals or the surroundings

- Electromagnetic Compatibility Tests to IEC 60601-1-2 (1992-06) to ensure no intolerable magnetic disturbances are introduced into its electromagnetic environment. (EMC Compliance Report No. M90632, 10th September, 1999 refers)

- Immunity Tests to IEC 60601-1-2 (1992-06) to ensure that the EEG equipment has the ability to operate satisfactorily in its electromagnetic environment

- Comparative tests were conducted on 20 volunteer patients at the Gold Coast Sleep Disorders Centre using the Nihon Kohden Polygraph and the Compumedics EEG System. The two systems were used to simultaneously record study data. Printouts from both systems were compared and shown to be equivalent.

- Compliance testing to Software Test Specification to ensure that the system conforms to all of the system design requirements.

- Y2K Tests to the Year 2000 Compliance Requirements

## 7. Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Compumedics that the Compumedics EEG System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Compumedics Neuro Science Pty Ltd.
c/o Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6470 Riverview Terrace
Minneapolis, Minnesota 55432

Re: K000068
Trade Name: E-Series EEG System
Regulatory Class: II
Product Code: GWQ
Dated: January 7, 2000
Received: January 10, 2000

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## B. INDICATIONS FOR USE

510(k) Number K000068

**Device Name:** EEG SYSTEM

**Indications for Use:**

The E-Series EEG System is intended for use as an aid in the diagnosis of neurological related disorders. The EEG System is only to be used under the direction and supervision of a physician, EEG technologist or clinician. It is a computer-based information management tool designed to record, display, retrieve and replay individual patient neurological data. It will not prevent or restore the interruption or loss of any physiological system.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000068

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)